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(12) **United States Patent**
Goldberger et al.

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(54) **FLUID ACCESS INTERFACE**

(75) Inventors: **Daniel Goldberger**, Boulder, CO (US); **Eric Shreve**, Louisville, CO (US); **Wayne Siebrecht**, Golden, CO (US); **Benny Pesach**, Rosh Ha'ayin (IL); **Gidi Pesach**, Kafar Vitikin (IL); **Gabby Bitton**, Jerusalem (IL); **Ron Nagar**, Tel Aviv (IL); **Dalia Argaman**, Hod-Hasharon (IL); **Stephen Bellomo**, Zirchron Yaacov (IL); **Robert Larson**, Salt Lake City, UT (US); **Larry Johnson**, Bennett, CO (US); **Jill Klomhaus**, Longmont, CO (US)

(73) Assignee: **IntelliDx, Inc.**, Santa Clara

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(51) **Int. Cl.**
A61B 5/00 (2006.01)

(52) **U.S. Cl.** **600/365**; 600/309; 600/575

(58) **Field of Classification Search** 600/345, 600/347, 365, 575; 604/6.11, 6.12
See application file for complete search history.

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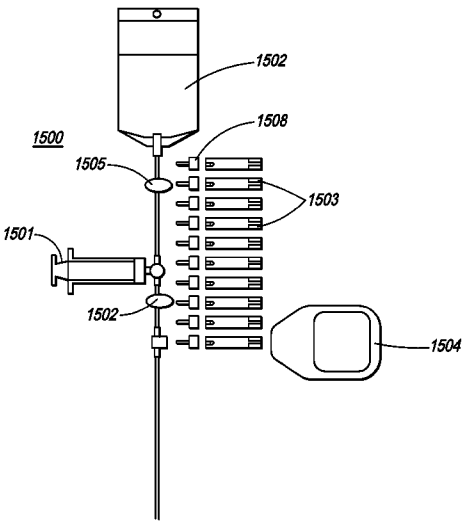
Primary Examiner — Patricia Mallari
(74) *Attorney, Agent, or Firm* — Morrison & Foerster LLP

(57) **ABSTRACT**

The present invention relates generally to systems, apparatuses, and methods for obtaining a fluid sample from a patient. In particular, the present invention relates to a various types of fluid access interfaces for enabling contact between a patient blood sample and blood parameter sensors for the measurement of physiological parameters and blood constituents.

13 Claims, 15 Drawing Sheets



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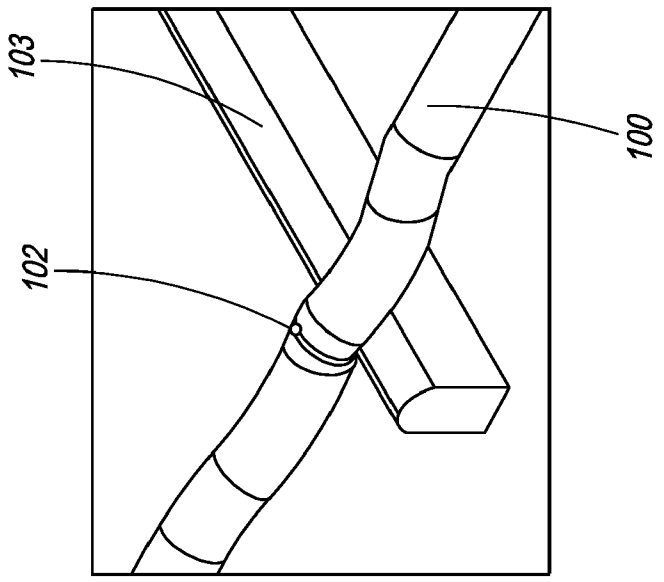

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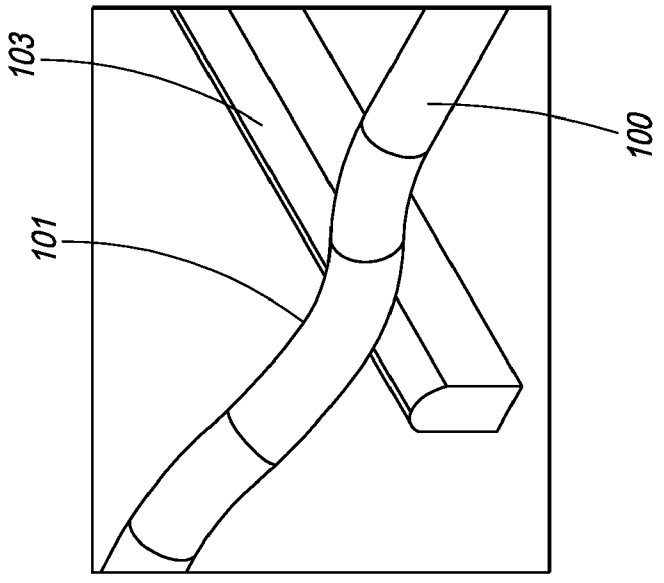


FIG. 1A

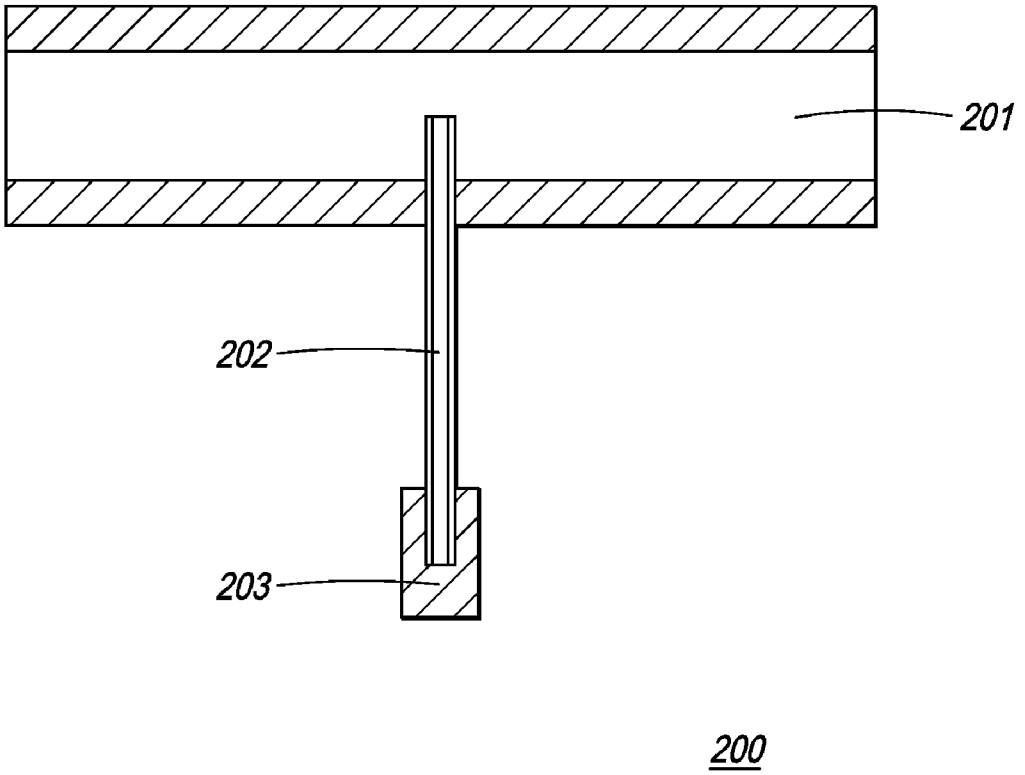
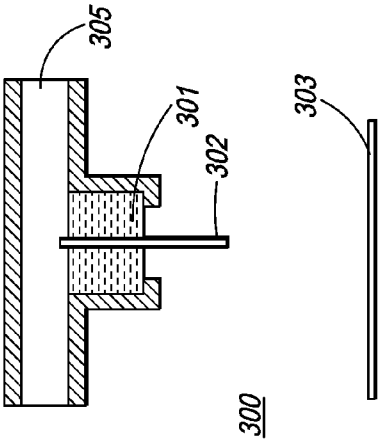


FIG. 2



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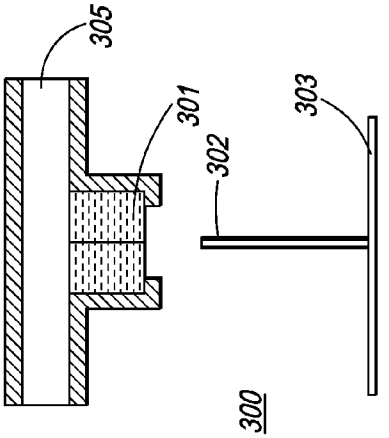


FIG. 3C

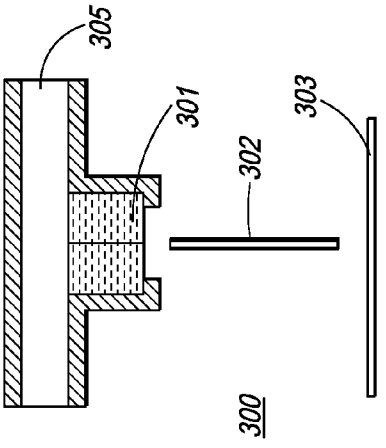
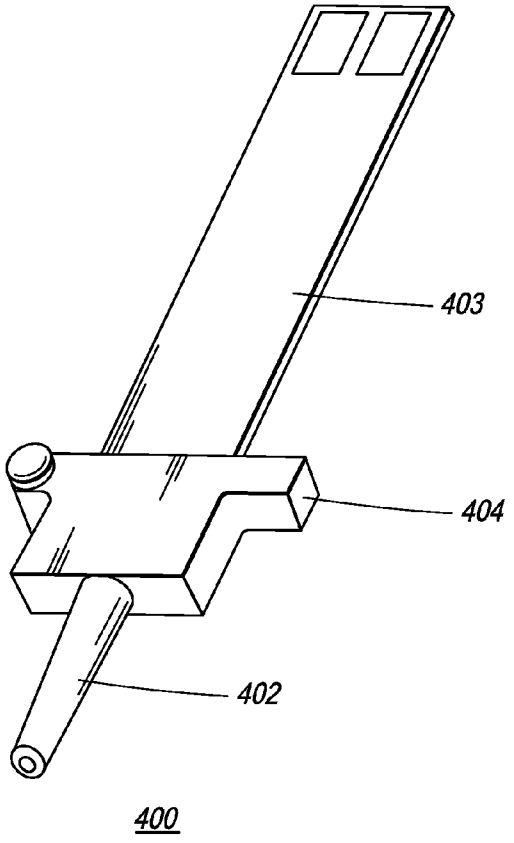


FIG. 3A



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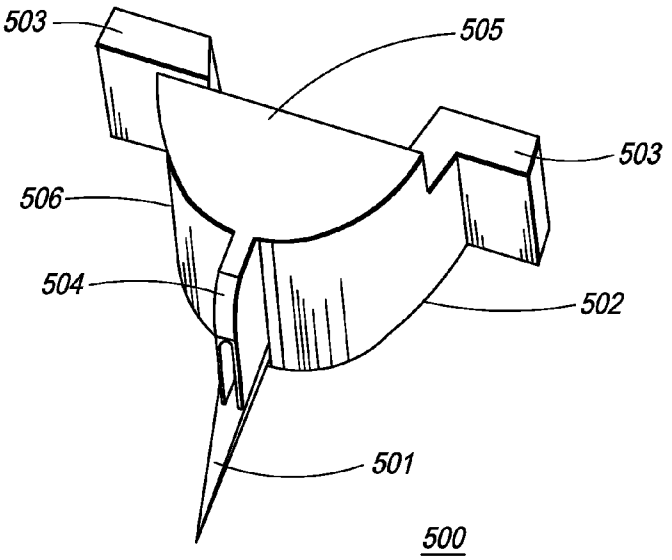

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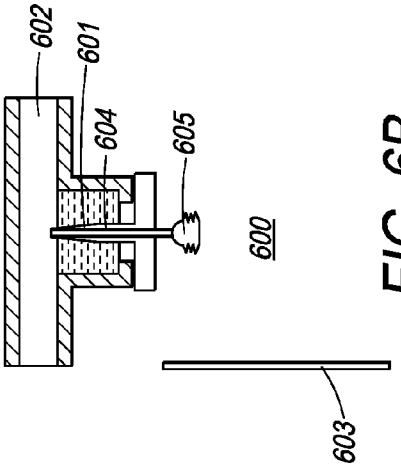

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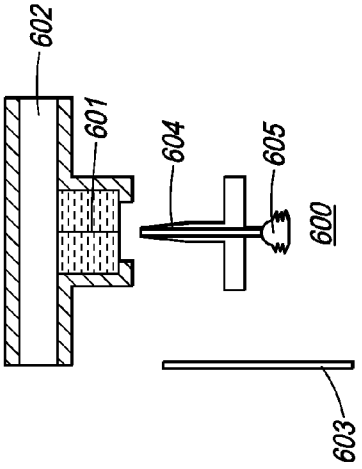


FIG. 6A

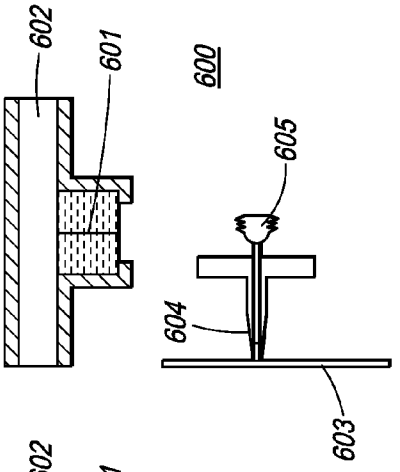


FIG. 6E

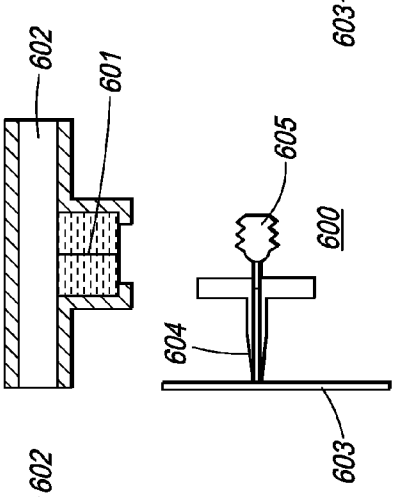


FIG. 6D

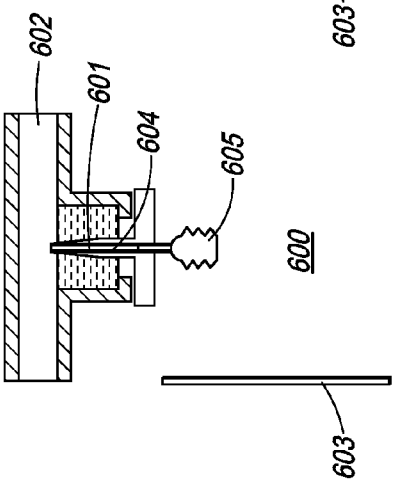
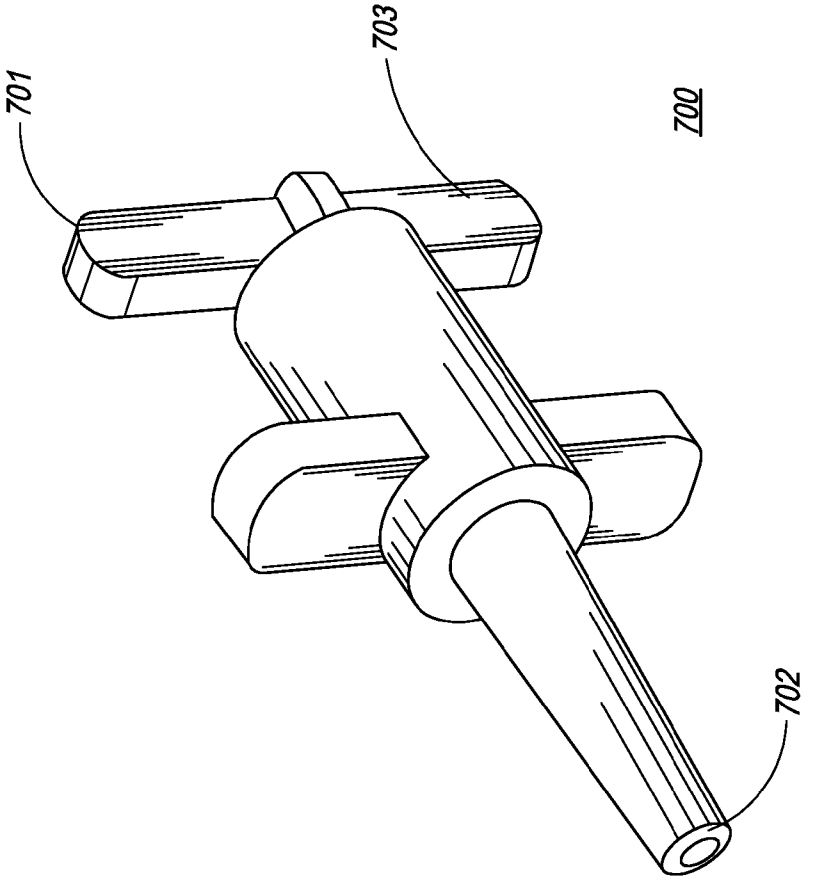


FIG. 6C



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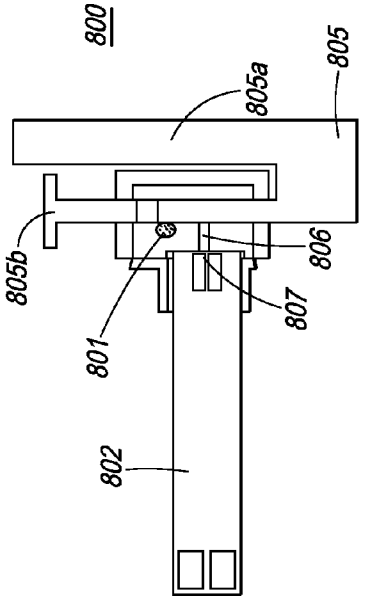


FIG. 8A

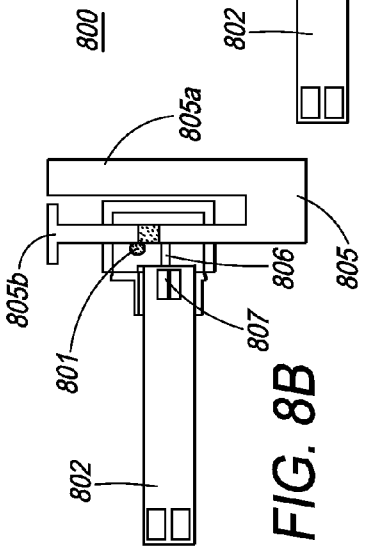


FIG. 8B

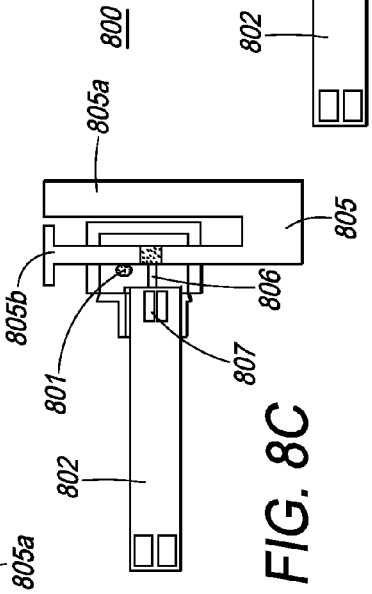


FIG. 8C

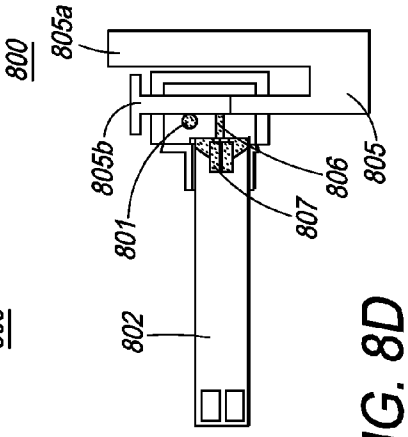


FIG. 8D

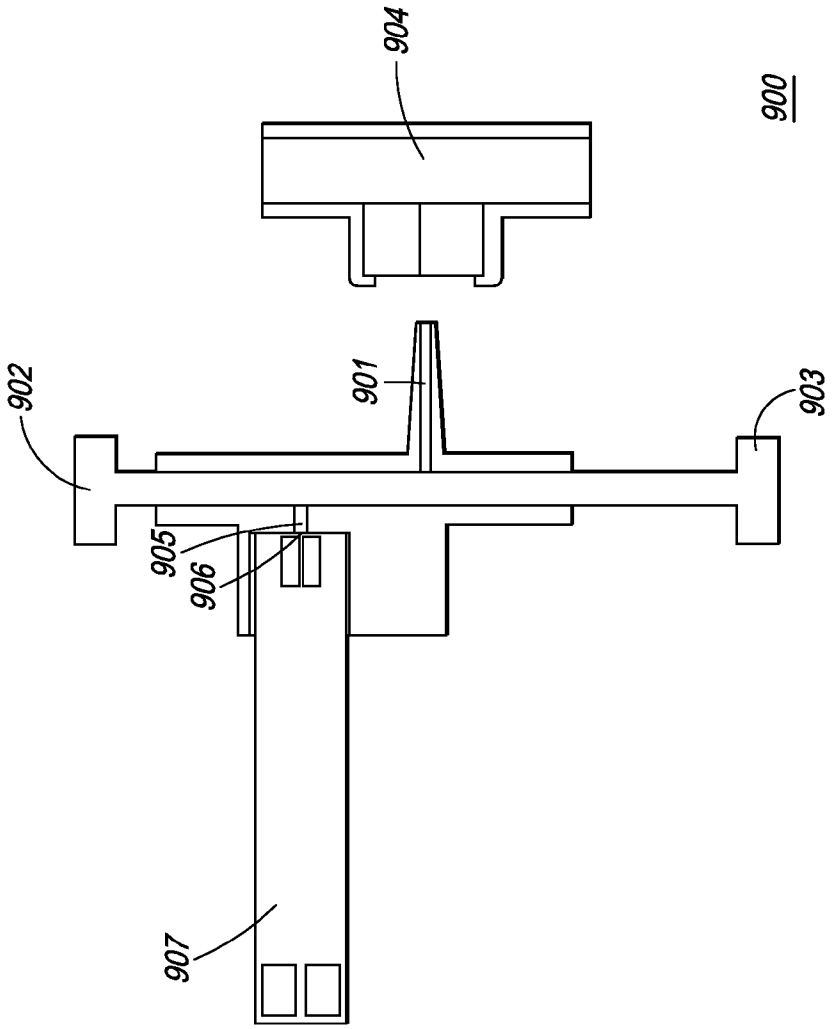


FIG. 9

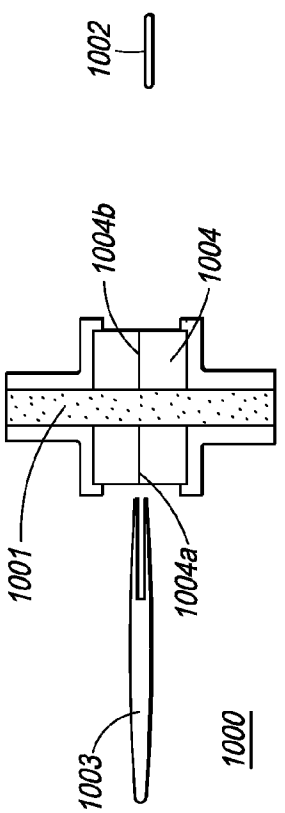


FIG. 10A

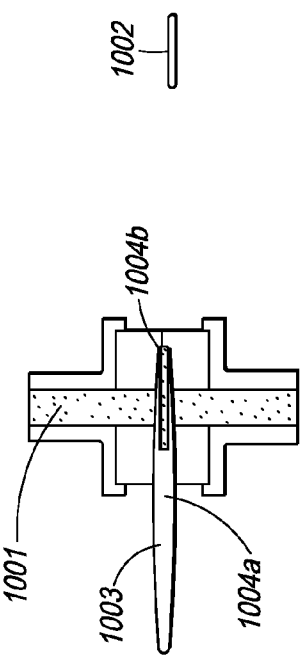


FIG. 10B

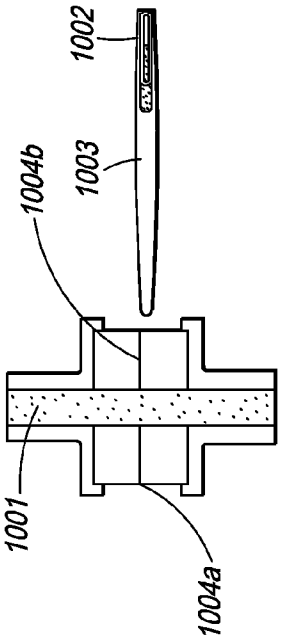


FIG. 10C

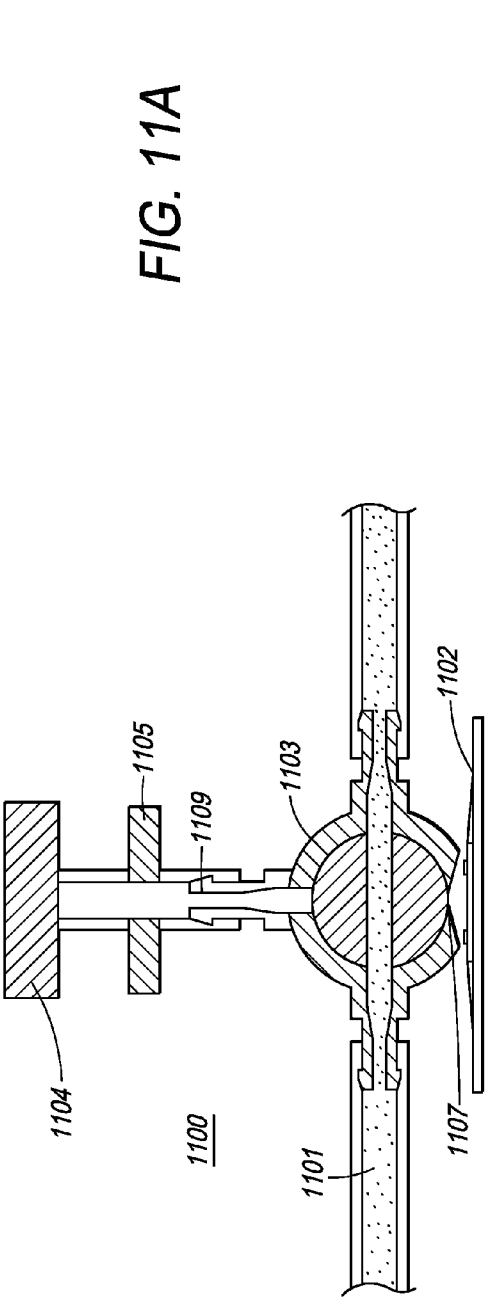


FIG. 11A

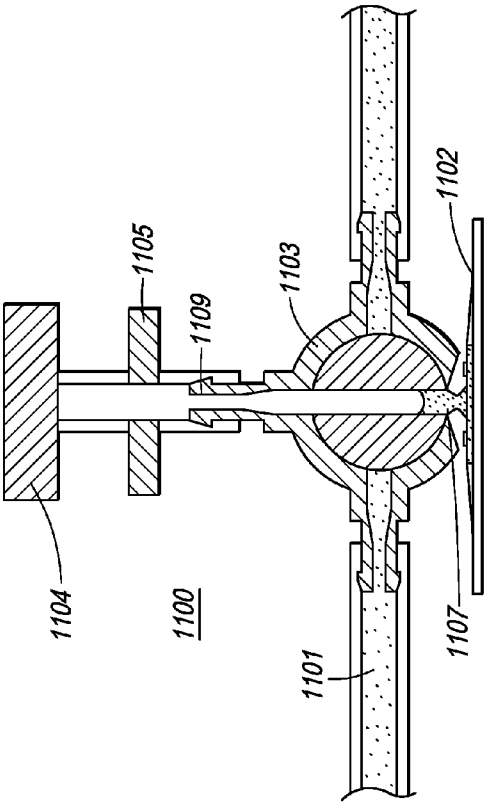
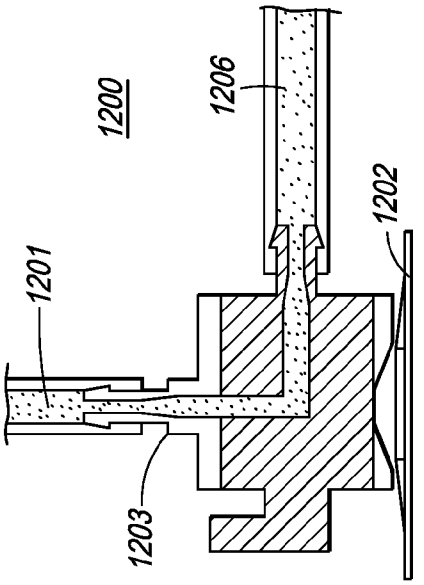


FIG. 11B

FIG. 12A



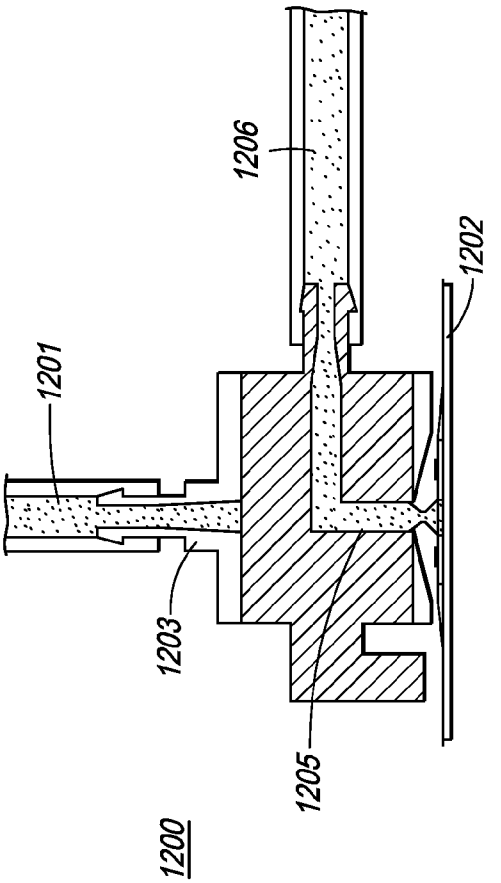


FIG. 12B

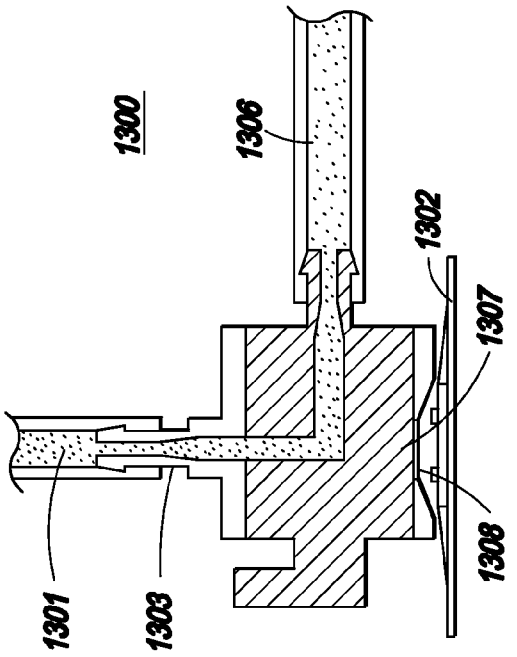


FIG. 13A

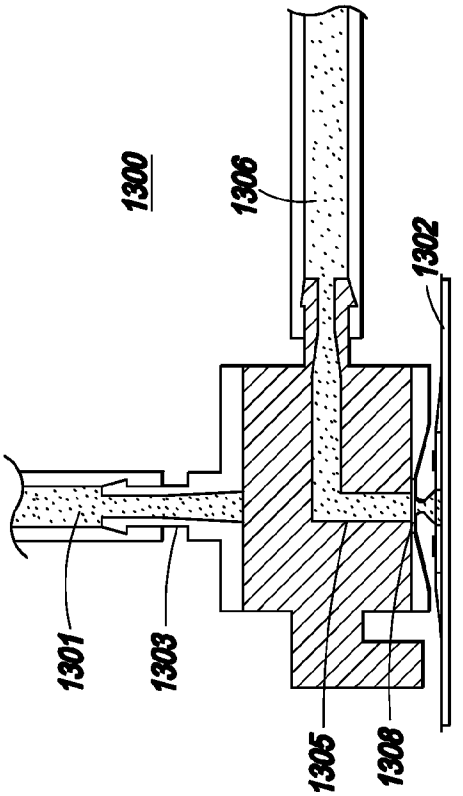


FIG. 13B

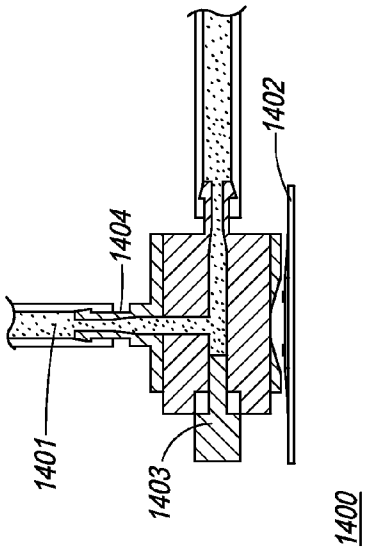


FIG. 14B

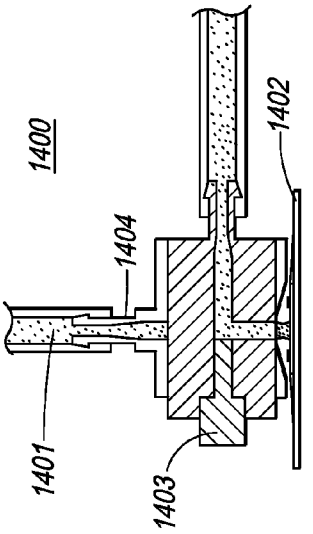


FIG. 14D

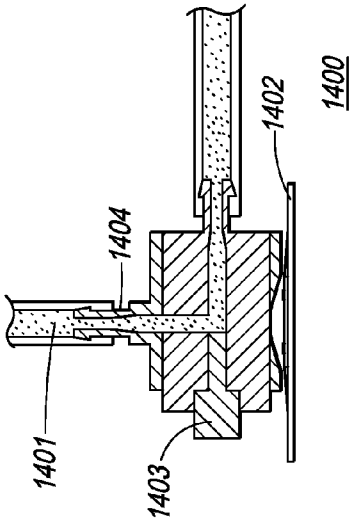


FIG. 14A

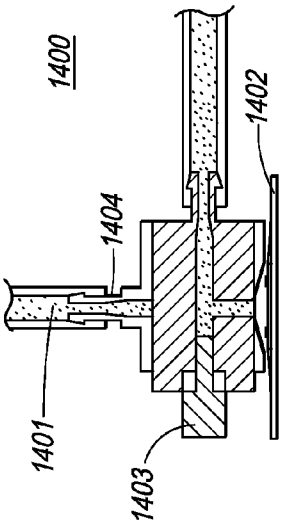


FIG. 14C

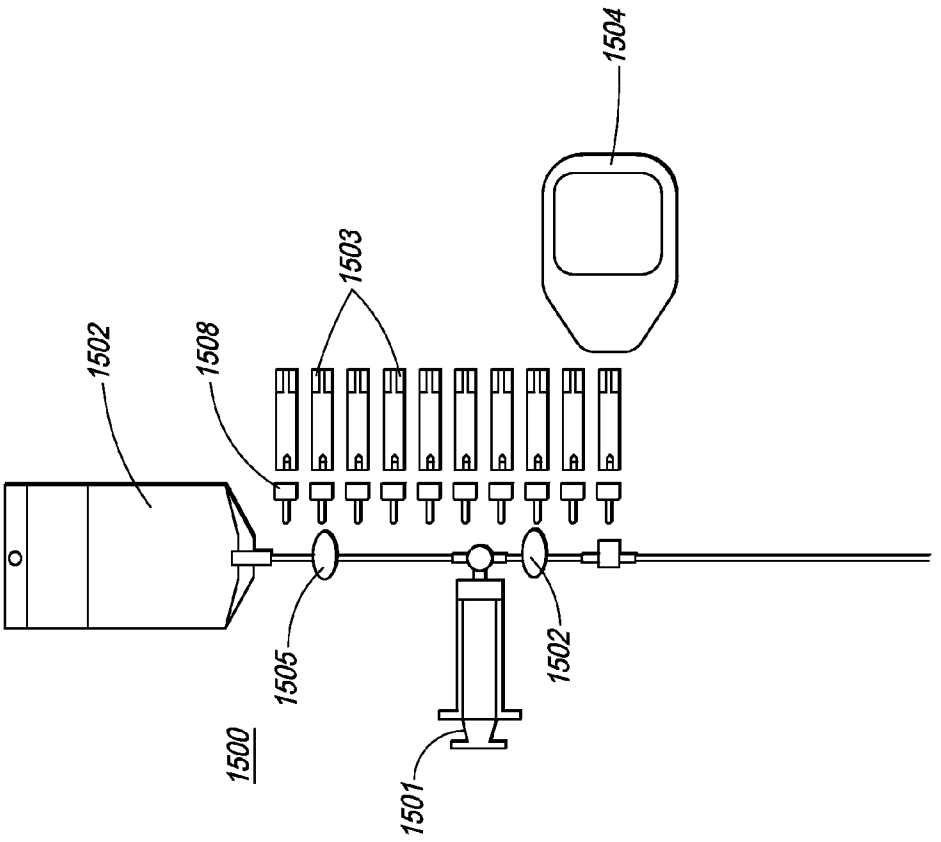


FIG. 15

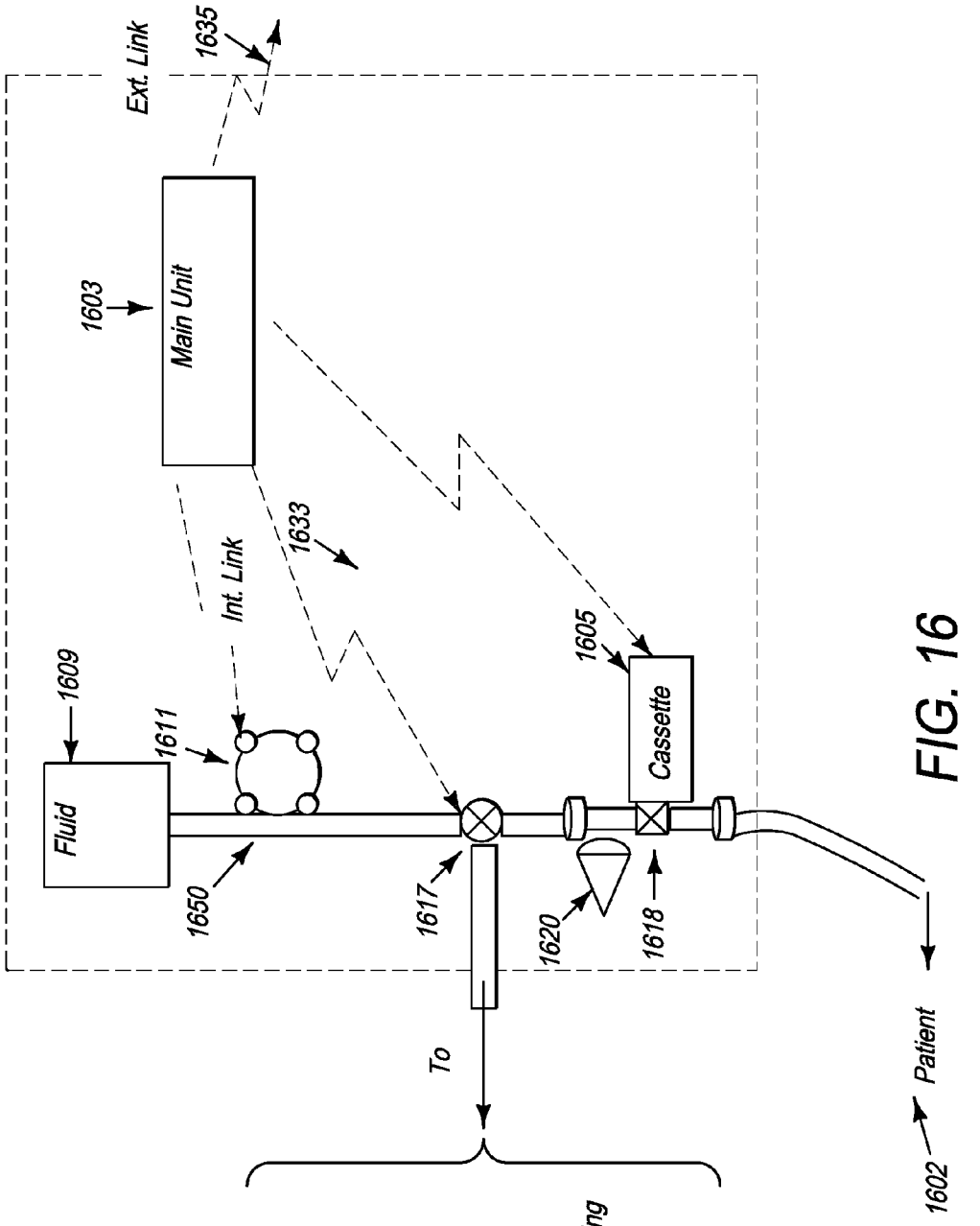

Ext. Link
1635
1603
Main Unit
1633
Int. Link
1609
1611
1605
Cassette
Fluid
1650
1617
1620
1618
To
External
Pressure Transducer
or
External Infusion
or
Manaul Blood Sampling
1602
Patient

FIG. 16

FLUID ACCESS INTERFACE

FIELD OF THE INVENTION

The present invention relates generally to systems, apparatuses, and methods for obtaining a fluid sample from a patient. In particular, the present invention relates to a fluid access interface for accessing a blood sample present in tubing, such as, for example, a vascular access line connected to a patient. In addition, the present invention relates to a fluid access interface for enabling contact between a patient blood sample and sensors, such as blood parameter testing strips, for the measurement of physiological parameters and blood constituents. More specifically, the fluid access interfaces of the present invention may be used in conjunction with a system for automated blood glucose measurement and testing.

BACKGROUND OF THE INVENTION

Patient blood chemistry and monitoring of patient blood chemistry are important diagnostic tools in patient care. For example, the measurement of blood analytes and parameters often give much needed patient information in the proper amounts and time periods over which to administer a drug. Blood analytes and parameters tend to change frequently, however, especially in the case of a patient under continual treatment, thus making the measurement process tedious, frequent, and difficult to manage.

Blood glucose levels must be maintained within a narrow range (about 3.5-6.5 mM). Glucose levels lower than this range (hypoglycemia) may lead to mental confusion, coma, or death. High glucose levels (hyperglycemia) have been linked to severe complications, including kidney damage, neural damage, and blindness.

Conventional glucose measurement techniques require lancing a convenient part of the body (normally a fingertip) with a lancet, milking the finger to produce a drop of blood, and depositing the drop of blood on a measurement device (such as an glucose testing strip). This lancing method is both painful and inconvenient for the patient. The pain and inconvenience has additional and more serious implications of noncompliance. Patients generally avoid maintaining the recommended regimen of blood glucose measurement and thereby run the risk of improper glucose levels and consequent harmful effects.

The conventional Point-of-Care (POC) techniques for diagnostic blood testing are routinely performed manually at the bedside using a small sample of blood.

SureStep® Technology, developed by Lifescan, is one example of a conventional Point-of-Care diagnostic system. The SureStep® Technology, in its basic form allows for simple, single button testing, quick results, blood sample confirmation, and test memory. In operation, the SureStep® Point-of-Care system employs three critical steps for performance. In a first step, the blood sample is applied to the test strip. The blood sample is deposited on an absorbent pad, which is touchable and promotes quick, convenient, and safe sample application. In addition, blood is retained and not transferred to other surfaces. The sample then flows one way through the porous pad to the reagent membrane, where the reaction occurs. The reagent membrane is employed to filter out red blood cells while allowing plasma to move through. In a second step, the glucose reacts with the reagents in the test strip. Glucose in the sample is oxidized by glucose oxidase (GO) in the presence of atmospheric oxygen, forming hydrogen peroxide (H_2O_2). H_2O_2 reacts with indicator dyes using

horseradish peroxidase (HRP), forming a chromophore or light-absorbing dye. The intensity of color formed at the end of the reaction is proportional to the glucose present in the sample.

In a third step, the blood glucose concentration is measured with SureStep® meters. Reflectance photometry quantifies the intensity of the colored product generated by the enzymatic reaction. The colored product absorbs the light—the more glucose in a sample (and thus the more colored product on a test strip), the less reflected light. A detector captures the reflected light, converts it into an electronic signal, and translates it into a corresponding glucose concentration. The system is calibrated to give plasma glucose values.

Prior art devices have conventionally focused upon manually obtaining blood samples from in-dwelling catheters. Such catheters may be placed in venous or arterial vessels, centrally or peripherally. For example, Edwards Life-Sciences' VAMP Plus Closed Blood Sampling System provides a safe method for the withdrawal of blood samples from pressure monitoring lines. The blood sampling system is designed for use with disposable and reusable pressure transducers and for connection to central line catheters, venous, and arterial catheters where the system can be flushed clear after sampling. The blood sampling system mentioned above, however, is for use only on patients requiring periodic manual withdrawal of blood samples from arterial and central line catheters that are attached to pressure monitoring lines.

The VAMP Plus design provides a needleless blood sampling system, employing a blunt cannula for drawing of blood samples. In addition, a self-sealing port reduces the risk of infection. The VAMP Plus system employs a large reservoir with two sample sites. Two methods may be used to draw a blood sample in the VAMP Plus Blood Sampling System. The first method, the syringe method for drawing blood samples, first requires that the VAMP Plus is prepared for drawing a blood sample by drawing a clearing volume (preferred methods provided in the literature). To draw a blood sample, it is recommended that a preassembled packaged VAMP Needle-Less cannula and syringe is used. Then, the syringe plunger should be depressed to the bottom of the syringe barrel. The cannula is then pushed into the sampling site. The blood sample is then drawn into the syringe. A Blood Transfer Unit is then employed to transfer the blood sample from the syringe to the vacuum tubes.

The second method allows for a direct draw of blood samples. Again, the VAMP Plus is first prepared for drawing a blood sample by drawing a clearing volume. To draw a blood sample, the VAMP Direct Draw Unit is employed. The cannula of the Direct Draw Unit is pushed into the sampling site. The selected vacuum tube is inserted into the open end of the Direct Draw Unit and the vacuum tube is filled to the desired volume.

The abovementioned prior art systems, however, have numerous disadvantages. In particular, manually obtaining blood samples from in-dwelling catheters tends to be cumbersome for the patient and healthcare providers.

In the light of above described disadvantages, there is a need for improved methods and systems that can provide comprehensive blood parameter testing.

What is also needed is a programmable, automated system and method for obtaining blood samples for testing certain blood parameters and data management of measurement results, thus avoiding human recording errors and providing for central data analysis and monitoring.

In addition, what is needed are systems, methods, and apparatuses for enabling fluid sampling in automated blood parameter testing systems.

More specifically, what is needed are fluid sampling interface apparatuses and methods for using such apparatuses with automated blood parameter testing systems.

SUMMARY OF THE INVENTION

The present invention is directed toward a plurality of embodiments capable of accessing a blood sample, present in a vascular access line connected to a patient, or any other form of tubing. In one embodiment, the present invention is a device for accessing a blood sample from a patient and measuring blood constituents, comprising a single use flexible transfer tube having a shape, wherein the single use transfer tube is used to provide a direct fluid flow path to a test substrate and wherein an alteration in the shape of the tube causes the tube to move from an open state to a closed state. In an open state, the tube provides a blood sample to a proximally located testing site, such as a testing strip or sensor.

In another embodiment, the present invention is a device for accessing a blood sample from a patient and bringing the blood samples to a transfer tube in combination with a test strip holder. The test strip holder positions a test strip for fluid dispensing and mechanical handling. The distal end may be an end-access capillary test strip for glucose measurement.

The transfer tube may be used to access fluid from a main fluid line to determine the concentration of at least one analyte, wherein the main fluid tube further comprises a tube originating from a vascular access point, a pump fixedly attached to the tube, a valve fixedly attached to the tube and located above the pump mechanism, at least one measurement element, a needle-less port, for accessing the main fluid tube; and an electronic meter.

In another embodiment, the present invention is directed toward a device for accessing a blood sample, present in a vascular access line connected to a patient or any other form of tubing and measuring blood constituents, comprising a transfer tube with a closed end used to remove fluid from a needle-less access port and to a test substrate, wherein the closed end of the transfer tube is a bulb which can be expanded and contracted to access a fluid sample.

Optionally, the transfer tube comprises a micro-syringe, wherein the micro-syringe comprises a plunger to remove and deposit a fluid sample onto a test substrate. The closed-end transfer tube is used to access fluid from a main fluid line to determine the concentration of at least one analyte, wherein the main fluid line further comprises a tube originating from a vascular access point, a pump fixedly attached to the tube, a valve fixedly attached to the tube and located above the pump mechanism, at least one measurement element, a needle-less port for accessing the main fluid line, and an electronic meter.

In another embodiment, the present invention is directed toward a device for accessing a blood sample, present in a vascular access line connected to a patient or any other form of tubing and measuring blood constituents, comprising a piston pump, wherein the piston pump is connected to a transfer tube and said piston pump is used to remove a fluid sample and deliver the fluid sample to a test substrate. The piston pump is used to access fluid from a main fluid line to determine the concentration of at least one analyte, wherein the fluid line is further used with a tube originating from a vascular access point, a pump fixedly attached to the tube, a valve fixedly attached to the tube and located above the pump mechanism, at least one measurement element, a needle-less port, for accessing the main fluid line, and an electronic meter.

In another embodiment, the present invention is directed toward a device for accessing a blood sample, present in a vascular access line connected to a patient or any other form of tubing and measuring blood constituents, comprising a shuttle, wherein said shuttle is a single-use device used to facilitate drawing a sanitary and uncontaminated fluid sample through a sampling port without passing back through the sampling port.

Optionally, the shuttle device penetrates through a dual-sided needle-less port. The shuttle device is used to access fluid from a main fluid line to determine the concentration of at least one analyte, wherein the fluid line is further used with a tube originating from a vascular access point, a pump fixedly attached to the tube, a valve fixedly attached to the tube and located above the pump mechanism, at least one measurement element, a dual-sided needle-less port, for accessing the main fluid line, and an electronic meter.

In another embodiment, the present invention is directed toward a device for accessing a blood sample, present in a vascular access line connected to a patient or any other form of tubing and measuring blood constituents, comprising an air jet fluid access port, which further comprises a valve and a low volume air pump. The air jet fluid access port is used to access fluid from a fluid line to determine the concentration of at least one analyte, wherein the fluid line is used with a tube originating from a vascular access point, a pump fixedly attached to the tube, a valve fixedly attached to the tube and located above the pump mechanism, at least one measurement element, a needle-less port, for facilitating access to the main fluid line, and an electronic meter.

In another embodiment, the present invention is directed toward a device for accessing a blood sample, present in a vascular access line connected to a patient or any other form of tubing and measuring blood constituents, comprising a distribution valve wherein said distribution valve is used to redirect a main flow of fluid to a side path. Optionally, the distribution valve is a by-pass valve. Optionally, the distribution valve has zero dead volume. Optionally, the distribution valve has a micro filter positioned at one or more ports. The micro-filter isolates the fluid inside the valve from contamination. The micro-filter is cleaned by purging fluid before and after sample collection. The distribution valve may include a sterile filter. The distribution valve may include a dispensing pump. The distribution valve is used to access fluid from a fluid line to determine the concentration of at least one analyte, wherein said line is used with a tube originating from a vascular access point, a pump fixedly attached to the tube, a valve fixedly attached to the tube and located above the pump mechanism, at least one measurement element, and an electronic meter.

In another embodiment, the disclosed inventions are used with an automated blood glucose analysis device further comprising an access device for gaining access to blood with a catheter; a pump to withdraw blood from the patient in a predetermined schedule; at least one sensor placed in contact with said blood by an action of the fluid access interfaces of the present invention; and a signal processor to measure a signal produced by the at least one sensor upon contact with said blood where the signal is indicative of said at least one predetermined parameter.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features and advantages of the present invention will be appreciated, as they become better understood by reference to the following Detailed Description when considered in connection with the accompanying drawings, wherein:

FIGS. **1**A and **1**B are illustrations of one embodiment of the fluid access interface device of the present invention, implemented as a flexible tube;

FIG. **2** depicts another embodiment of the fluid access interface device of the present invention;

FIGS. **3**A, **3**B, and **3**C illustrate the structure and operational steps of one embodiment of the fluid access interface device of the present invention;

FIG. **4** illustrates another embodiment of the fluid access interface device of the present invention implemented as a transfer tube with an integrated test strip holder;

FIG. **5** illustrates a lancet structure;

FIGS. **6**A, **6**B, **6**C, **6**D, and **6**E depict the structure and operational steps of one embodiment of the fluid access interface of the present invention implemented as a transfer tube with one closed end;

FIG. **7** depicts another embodiment of the fluid access interface of the present invention implemented as a transfer tube equipped with a micro-syringe on one end;

FIGS. **8**A, **8**B, **8**C, and **8**D depict the structure and operational steps of one embodiment of the fluid access interface device of the present invention wherein a pump is employed;

FIG. **9** is a cross-sectional view of one embodiment of the fluid access interface of the present invention implemented as a transfer tube equipped with a pump;

FIGS. **10**A, **10**B, and **10**C depict the structure and operational steps of one embodiment of the fluid access interface of the present invention wherein a shuttle and dual needle-less port are employed;

FIGS. **11**A and **11**B depict the structure and operational steps of one embodiment of the fluid access interface of the present invention implemented as an air jet fluid access port;

FIGS. **12**A and **12**B depict the structure and operational steps of one embodiment of the fluid access interface of the present invention wherein a distribution valve is employed;

FIGS. **13**A and **13**B depict the structure and operational steps of another embodiment of the fluid access interface of the present invention, implemented as a distribution valve equipped with a filter;

FIGS. **14**A, **14**B, **14**C, and **14**D depict the structure and operational steps of one embodiment of the fluid access interface of the present invention implemented as a distribution valve with an integrated dispensing pump;

FIG. **15** is a schematic diagram of an exemplary embodiment of an automated blood parameter testing apparatus for use with the present invention; and

FIG. **16** is a schematic diagram of another exemplary embodiment of an automated blood parameter testing apparatus for use with the present invention.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is directed towards an integrated, automated system for measurement and analysis of blood analytes and blood parameters. The present invention is also directed towards an automated blood parameter testing apparatus portion of the automated blood parameter analysis and measurement system. More specifically, the present invention is directed towards methods, apparatuses, and systems for accessing a blood sample, present in a vascular access line connected to a patient or any other form of tubing via a fluid access interface. In one embodiment, the fluid access interface methods, apparatuses, and systems are used for automated blood glucose testing.

In automatic operation, when fluid sampling is initiated, either by a pre-determined, programmed schedule or via operator input, the fluid access interface is activated and a fluid sample is drawn from the vascular access line connected to a patient or any other form of tubing. The system operates automatically to draw the fluid samples via a fluid access interface at suitable, programmable frequencies to analyze the drawn blood samples and obtain the desired blood readings such as glucose levels, hematocrit levels, hemoglobin blood oxygen saturation, blood gasses, lactates or any other parameter as would be evident to persons of ordinary skill in the art.

As referred to herein, the terms "blood analyte(s)" and "blood parameter(s)" refers to such measurements as, but not limited to, glucose level; ketone level; hemoglobin level; hematocrit level; lactate level; electrolyte level (Na^+, K^+, Cl^-, Mg^{2+}, Ca^{2+}); blood gases (pO_2, pCO_2, pH); cholesterol; bilirubin level; and various other parameters that can be measured from blood or plasma samples. The term "vascular access point(s)" refer to venous or arterial access points in the peripheral or central vascular system.

Reference will now be made in detail to specific embodiments of the invention. While the invention will be described in conjunction with specific embodiments, it is not intended to limit the invention to one embodiment. Thus, the present invention is not intended to be limited to the embodiments described, but is to be accorded the broadest scope consistent with the disclosure set forth herein.

In one embodiment, the present invention is a device for accessing a blood sample from a patient and measuring blood constituents, wherein the fluid access interface comprises a flexible transfer tube having a shape, wherein the transfer tube is used to provide a direct fluid flow path to a test substrate and wherein an alteration in the shape of the tube causes the tube to move from an open state to a closed state. In an open state, the test tube substrate provides a blood sample to a proximally located testing site, such as a testing strip or sensor.

FIGS. **1***a* and **1***b* are illustrations of one embodiment of the fluid access interface of the present invention, wherein the flexible tube is employed. In a first embodiment, a fluid access interface is implemented as a flexible tube. Specifically, FIG. **1***a* is a depiction of flexible tube **100** wherein outlet **101** is in a closed state. FIG. **1***b* is a depiction of a bent flexible tube **100** wherein outlet **102** is in an open state. An alteration in the shape of the tube facilitates control of the outlet. The alteration of the tube shape can be facilitated by a member **103**, which can be any structure, including a rod, stick, lever, or any linear extension. When flexible tube **100** is bent, as shown in FIG. **1***b*, the tube is split open, creating an open state and thus forming an outlet for a fluid sample. In an open state, outlet **102** may comprise a slit or hole, however, the opening is not limited to such configurations.

FIG. **2** depicts another embodiment of a fluid access interface **200** wherein a transfer tube is employed. A fluid access interface is implemented as a transfer tube equipped with a cap or valve, used to extract fluid from a vascular access line connected to a patient or any other form of tubing. As shown in FIG. **2**, the main fluid line **201** further comprises transfer tube **202**, and end valve **203**. In one embodiment, main fluid line **201** is a vascular access line connected to a patient. Preferably, transfer tube **202** is smaller in diameter than main fluid line **201**. End valve **203** is used to draw fluid into transfer tube **202** for subsequent collection. When the transfer tube **202** is not in use, end valve **203** may serve as a cap, thus providing a sealed, sterile barrier.

FIGS. **3***a*, **3***b*, and **3***c* illustrate the structure and operational steps of another embodiment of the fluid access interface of the present invention wherein a transfer tube is employed. As shown in FIG. **3***a*, the fluid access interface device **300** of the present invention is implemented as a transfer tube that is

used to remove fluid from a main fluid line **305** connected to a patient. Main fluid line **305** further comprises seal **301**. In one embodiment, seal **301** is a needle-less access port. The transfer tube **302** is positioned to come into contact with seal **301**, extract a fluid sample (not shown) from main line **305**, and subsequently deliver the fluid sample to a test substrate **303**.

FIG. **3***b* illustrates fluid access interface device **300** in operation. The transfer tube **302** penetrates seal **301**, accessing main fluid line **305**. The transfer tube **302** is thus used to provide a direct flow path to the test substrate **303**. As shown in FIG. **3***c*, after single use transfer tube **302** comes into contact with main fluid line **305**, and more specifically, seal **301**, transfer tube **302**, now containing fluid, is extracted from seal **301**. Single use transfer tube **302** subsequently transports fluid to the test substrate **303**. After removal from the test unit, transfer tube **303** is disposed into an appropriate container.

FIG. **4** illustrates another embodiment of a fluid access interface device **400** wherein a transfer tube **402** is integrated with a test strip holder **404**. The integrated transfer tube **402** and test strip holder **404** is employed to access a fluid sample present in a vascular access line [not shown] connected to a patient or any other form of tubing. As previously shown, the main fluid line or vascular access line is preferably accessed via a needle-less port or seal. The integrated transfer tube **402** and test strip holder **404** is employed to position the test substrate **403** for proper fluid dispensing and mechanical handling. In one embodiment, the device **400** minimizes the amount of fluid required in a sample by reducing the dead volume of the structure and is optimally designed so that fluid flow is not impeded. Device **400** is also optimally shaped to effectuate capillary flow. Excess fluid resides in the area around the test substrate and single use transfer tube. The operation of the transfer tube has already been described with respect to FIG. **3** and will not be repeated herein. In operation of device **400**, the fluid is delivered to the test substrate **403** via the transfer tube **402**.

FIG. **5** illustrates a portion of one embodiment of a fluid access interface designed to access a blood sample through the skin of a person. Lancet **500** is used to access a blood sample by using sharp protusion **501** to enter through a patient's skin. Sharp protusion **501** is physically integrated with edge **504** that is attached to structure **502**. Structure **502** comprises a curved base **506** and two faces **505** curved to conform to the shape of the curved base **506** and having a linear top side. Integrally formed with the structure **502** are handles **503** which are flattened protusions designed to allow a person or mechanical actuator to hold and push the sharp protusion **501** into a patient's skin.

FIGS. **6***a*, **6***b*, **6***c*, **6***d*, and **6***e* illustrate the operational steps of one embodiment of the fluid access interface device of the present invention implemented as a transfer tube with a closed end forming a bulb. As shown in FIG. **6***a*, device **600** is a fluid access interface for accessing a blood sample, present in a main fluid line connected to a patient or any other form of tubing. In one embodiment, the fluid access interface **600** accesses the fluid sample from a needle-less access port or seal **601** attached to main fluid line **602**. The fluid sample is subsequently delivered to test substrate **603**. In one embodiment, fluid access interface device **600** comprises a transfer tube **604** with closed end **605**, which is flexible and can be expanded and contracted to access a fluid sample and subsequently deposit the sample on a test substrate.

As shown in FIG. **6***b*, in operation, transfer tube **604** of device **600** is used to penetrate the needle-less access port or seal **601** of main fluid line **602**. Now referring to FIG. **6***c*, closed end **605** of device **600** is expanded, thus withdrawing a fluid sample. As shown in FIG. **6***d*, the device is removed from the needle-less access port **601** and positioned on the test substrate **603**. Finally, as shown in FIG. **6***e*, the closed end **605** of the device **600** is contracted depositing the fluid on the test substrate.

FIG. **7** depicts one embodiment of the fluid access interface of the present invention implemented as a transfer tube equipped with a micro-syringe on one end. The fluid access interface is employed to access a fluid sample, present in a main fluid line connected to a patient or any other form of tubing. In one embodiment, the fluid access interface **700** accesses the fluid sample from a needle-less access port (not shown) attached to the main fluid line (not shown) and delivers the fluid sample to a test substrate using a plunger-type device that regulates fluid volume. Device **700** comprises two ends—a distal end **701** and a proximate end **702**. Proximate end **702** is preferably sized and shaped to penetrate a needle-less access port (not shown). Distal end **701** further comprises plunger **703**, which is pulled and pushed to remove and deposit the fluid sample on the test substrate. Fluid access interface device **700** is similar in operation to the device described above with respect to FIG. **6** and thus, operational characteristics will not be repeated herein.

FIGS. **8***a*, **8***b*, **8***c*, and **8***d* illustrate the structure and operational steps of one embodiment of the fluid access interface of the present invention. The fluid access interface, implemented as a piston pump, is employed to access a fluid sample, present in a main fluid line connected to a patient or any other form of tubing. In one embodiment, the fluid access interface **800** accesses the fluid sample from a needle-less access port or seal attached to the main fluid line and delivers the fluid sample to a test substrate.

Referring now to FIG. **8***a*, a fluid sample is transferred from main fluid line **801** to a test substrate **802**, via fluid access interface **800**. In one embodiment, fluid access interface **800** comprises piston **805**. Piston **805** further comprises piston chamber **805***a* and piston pump **805***b*. Piston **805** is employed to draw a bolus of fluid (not shown) from the main fluid line **801** into a cylinder **806**, as shown in FIG. **8***b*. As shown in FIG. **8***c*, the bolus of fluid is then transported to the opening of test port **807** through cylinder **806**. The bolus of fluid is then pushed to test substrate **802**, as shown in FIG. **8***d*. Fluid access interface **800** may be implemented in several configurations, including, but not limited to multiple-use or single-use and/or with a multiple device configuration, such as a stack.

FIG. **9** is a cross-sectional view of one embodiment of the fluid access interface device of the present invention wherein a transfer tube further comprising a piston pump is employed to access a fluid sample, present in a main fluid line connected to a patient or any other form of tubing. In one embodiment, the fluid access interface **900** accesses the fluid sample from a needle-less access port or seal attached to the main fluid line and delivers the fluid sample to a test substrate.

Fluid access interface device **900** comprises a transfer tube **901** and pistons **902** and **903**. Pistons **902** and **903** draw a bolus of fluid from main fluid line **904** via transfer tube **901** into a cylinder **905**. The drawn bolus of fluid is then transported alongside cylinder **905** to the test access port entrance **906** and subsequently pushes the fluid through to test substrate **907**. Device **900** can be employed in many configurations, including, but not limited to multiple-use or single-use with a multiple device configuration, such as a stack.

FIGS. **10***a*, **10***b*, and **10***c* depict the structure and operational steps of one embodiment of the fluid access interface of the present invention. The fluid access interface **1000** is employed to access a fluid sample, present in a main fluid line connected to a patient or any other form of tubing. In one

embodiment, the fluid access interface **1000** accesses the fluid sample from a dual-sided needle-less access port or seal **1004** attached to the main fluid line **1001** via shuttle **1003** and delivers the fluid sample to a test substrate [not shown].

Referring to FIG. **10***a*, apparatus **1000** is used to transfer a fluid sample from main fluid line **1001** to test substrate **1002**. Shuttle device **1003** is employed to penetrate first membrane **1004***a* of the dual-sided needle-less port or seal **1004** and access fluid. As shown in FIG. **10***b*, shuttle device **1003** passes into first membrane **1004***a* of dual-sided needle-less port or seal **1004** and collects a fluid sample. Shuttle device **1003** then passes through second membrane **1004***b* of dual-sided needle-less port or seal **1004** and delivers the sample to test substrate **1002**, as shown in FIG. **10***c*. Shuttle device **1003** is a single-use device employed to facilitate a sanitary and uncontaminated fluid sample without passing back through the sample port.

FIGS. **11***a* and **11***b* illustrate the structure and operational steps of another embodiment of the fluid access interface of the present invention wherein an air jet fluid access port is employed. The fluid access interface is used to access a fluid sample, present in a main fluid line connected to a patient or any other form of tubing. In one embodiment, the fluid access interface **1100** accesses the fluid sample from an air jet fluid access port attached to the main fluid line and delivers the fluid sample to a test substrate. Fluid access interface device **1100** comprises valve **1103** used to remove a volume of fluid from the main fluid line **1101** through an exit port **1107** to a substrate **1102**. Valve **1103** rotates from a first state, shown in FIG. **11***a*, to a second state, shown in FIG. **11***b*, which aligns a collected sample with exit port **1107** and air pump inlet **1109**. A low volume air pump **1104** then pushes the fluid sample through the inlet **1109** onto the test substrate **1102**, as shown in FIG. **11***b*. A micro-filter **1105** is preferably employed to ensure that no contamination enters the system or the fluid sample. Valve **1103** then returns to the first state from the second state after disbursing the blood sample on substrate **1102**.

FIGS. **12***a* and **12***b* depict the structure and operational steps of another embodiment of the fluid access interface of the present invention wherein a distribution valve is used. The fluid access interface is employed to access a fluid sample, present in a main fluid line connected to a patient or any other form of tubing. Fluid access interface **1200** accesses the fluid sample from the main fluid line **1201** and delivers the fluid sample to a test substrate **1202**. As shown in FIG. **12***a*, device **1200** comprises a by-pass distribution valve **1203**, employed to access fluid from main fluid access line **1201** and deliver it to test substrate **1202**. Valve **1203** is used to divert fluid flow to a side path **1205**, as shown in FIG. **12***b*. The fluid sample is then pushed onto the test substrate **1202** via the side path with a pump (not shown).

FIGS. **13***a* and **13***b* illustrate the structure and operational steps of another embodiment of the fluid access interface of the present invention wherein the distribution valve shown in FIG. **12** is further equipped with a sterile filter. The operational steps are similar to those described in detail with respect to FIG. **12**. The details will only be described herein where necessary to differentiate this embodiment from that described with respect to FIG. **12**.

Referring now to FIG. **13***a*, device **1300** is employed to access fluid from main fluid line **1301** and deliver the fluid sample to test substrate **1302**. Valve **1303** is used to divert the flow of fluid from main fluid line **1301** to a side path **1305**. Pump [not shown] is then used to push the fluid sample onto a test substrate **1302**. Valve **1303** also contains an opening **1307**, where the fluid sample exits to contact the test substrate **1302**. At opening **1307**, device **1300** further comprises micro-filter **1308** through which the fluid sample passes prior to coming into contact with test substrate **1302**. Micro-filter **1308** serves to protect the fluid inside valve **1303** from contamination. FIG. **13***b* illustrates the fluid sample coming into contact with the test substrate **1302**. In one embodiment, micro-filter **1308** is cleaned via purging clean fluid (not blood) before and after sample collection onto a "purge pad" (not shown) for disposal. The micro-filter **1308** is cleaned when the valve **1303** is rotated back to "by-pass flow" position.

FIGS. **14***a*, **14***b*, **14***c*, and **14***d* depict the structure and operational steps of one embodiment of the fluid access interface of the present invention employing a distribution valve, such as that shown in FIGS. **12** and **13**, further equipped with an integrated dispensing pump. As shown in FIG. **14***a*, device **1400** is used to access fluid from a main fluid line **1401** and deliver the fluid sample to a test substrate **1402**. As shown in FIG. **14***b*, plunger **1403** on an internal pump (not shown) is pulled to obtain a fluid sample. Valve **1404** is rotated to divert the main flow of fluid to a side path, as shown in FIG. **14***c*. The fluid sample is subsequently pushed onto the test substrate **1402** with plunger **1403**, as depicted in FIG. **14***d*.

FIG. **15** illustrates one embodiment of an exemplary automated blood parameter testing apparatus for use with the fluid access interface of the present invention. U.S. patent application Ser. No. 11/157,110, assigned to Applicant, is herein incorporated by reference. The invention therein is directed towards an automated blood parameter testing apparatus in which a blood parameter measurement element is employed.

As shown in FIG. **15**, in one exemplary embodiment, the various embodiments of the fluid access interface of the present invention are used with an automated blood parameter testing apparatus **1500**. In one embodiment, the automated blood parameter testing apparatus is a glucose meter **1504**. In another embodiment, the blood parameter testing apparatus **1500** is used with any one of the fluid access interfaces **1508** disclosed herein. In one embodiment, a glucose testing strip **1503** is in fluid communication with the fluid access interface **1508**. The fluid is moved from infusion bag **1502** into a patient [not shown] and blood samples are retrieved from a patient using a pump **1501**, preferably a syringe pump. A plurality of valves **1505** may be used to control fluid flow from either the infusion bag **1502** or patient [not shown]. The automated device **1500** is programmable to initiate a sample reading periodically or via operator input. Operator input is initiated by, but not limited to, the push of a button. In addition, operator input may be initiated at the central monitoring station.

FIG. **16** illustrates another embodiment of an exemplary automated blood parameter testing apparatus for use with the fluid access interface of the present invention. U.S. patent application Ser. No. 11/048,108, assigned to Applicant, is herein incorporated by reference. The invention therein is directed towards an automated blood parameter testing apparatus in which a blood parameter measurement element is employed.

As shown in FIG. **16**, in one exemplary embodiment, the various embodiments of the fluid access interface of the present invention are used with an automated blood parameter testing apparatus **1600**. It is to be understood that such embodiment is exemplary, but not limiting, and that the automated blood analysis device **1600** may be connected to other external devices at the same vascular access point. Automated blood analysis device **1600** blocks the operation of any connected infusion and/or external device (such as an external pressure transducer) during the period of blood sampling, in

order to ensure that the blood sample is not diluted/altered by other fluids injected in the patient.

During normal operation, pump **1611** drives fluid from infusion bag **1609** through a main line **1650** and into the patient **1602**. A first stopcock **1617** blocks fluid from traveling out of the main line **1650** and is periodically opened to permit an external infusion, manual blood sampling, or the measurement of pressure using an external transducer.

When performing automated blood sampling and measurement of required blood analytes, main unit **1603** directs pump **1611** to reverse, thereby reversing the flow of fluid. Main unit **1603** communicates with the valve **1617**, pump **1611**, and sensor cassette **1605** using internal links **1633** which can be wired or wireless. It further communicates to external monitoring stations using external link **1635**. Once the pump **1611** reverses operation, blood is pulled from patient **1602** into the main line **1650**. The blood is drawn along the tube until the remaining infusion volume and the initially diluted blood volume passes fluid access interface **1618** which is proximate to sensor cassette **1605**. A pressure measurement element can be used to ensure pressure does not increase excessively.

Main unit **1603** calculates the required volume of blood to be withdrawn based on the diameter and length of the tubing and according to a programmable dead-space volume, which can be either pre-calibrated or user-defined. Optionally, a blood presence sensor **1620** can be used to establish whether undiluted blood has reached the tube segment proximal to the fluid access interface **1618**. When undiluted blood reaches the fluid access interface **1618**, the fluid access interface is activated to obtain an undiluted blood sample for measurement by the sensor cassette **5**. The fluid access interfaces disclosed herein may be used obtain the undiluted blood samples.

When the undiluted blood sample is taken inside sensor cassette **1605** (by fluid access interface mechanism **1618**), a sensor (from a plurality of sensors within sensor cassette **1605**) is placed into contact with the drawn blood sample. Sensor is preferably, but not limited to, a single use sensor, and is used to measure patient blood analyte(s) and blood parameter(s). Sensor is preferably a component of a manual test device, such as, but not limited to glucose test strips for measuring glucose levels.

While the blood sample is analyzed, blood withdrawal from patient **1602** is stopped and main unit **1603** reverses the operation of pump **1611**. The tubing components, including line **1650**, are then flushed by purging fluid from fluid bag **1609**. The remaining blood in line **1650** may be infused back into patient **1602**.

Single use sensors are preferably packaged into disposable cassette **1605** and replaced periodically. Sensor cassette **1605** is preferably sterile, and is also preferably disposed after use with a single patient **1602**. Sensor cassette **1605** supports at least one or a plurality of single use sensors that are advanced sequentially and positioned for direct contact with the drawn blood sample. After completing a measurement, the used sensor is automatically advanced from the measurement location to a location for disposed sensors. Between measurements, the system moves a new sensor forward into contact with fluid access interface **1618**, thus replacing the one used in the previous measurement. Various cassette sizes can be manufactured and sensor cassette **1605** can be available, but is not limited to 25, 50, or 100 measurement capacities. In one design, sensor cassette **1605** also stores the consumed test supplies and sample waster.

The use of single-use sensors (similar to the use of finger stick sensors) eliminates the need for time-consuming operator-directed calibration procedures. In particular, each sensor cassette **1605** can be factory pre-calibrated. Optionally, sensor cassette **1605** or plurality thereof and individual sensors **1619** of the same type have the same pre-calibration values. Main display and control unit **1603** can automatically read the cassette factory calibration values by standard means well-known to those of ordinary skill in the art, such as by reading the data from a barcode or an EPROM embedded in sensor cassette **1605**. Optionally, factory values may be entered manually.

In addition, sensor cassette **1605** may be hermetically sealed and/or include humidity controls means, such as, but not limited to a small bag of dessicant material. In another option, each sensor or a portion thereof, may be contained in a packaging that is automatically opened prior to measurement. Optionally, the measurement portion of the sensors can be covered with a thin layer that protects the reagent area against moisture and/or light during storage (particularly useful for both electrochemical and optochemical sensors). The thin protective layer can be automatically peeled off by a peeling element (not shown), prior to the sensor being placed in position for measurement. The peeling element may comprise, but is not limited to, an edge-knife element strategically placed inside sensor cassette **1605**.

When using electrochemical sensors, sensor cassette **1605** includes an electronic interface to main unit **1603** of automated blood analysis device **1600**. When using optochemical or optical sensors, an electronic interface is optional, and sensor cassette **1605** can be designed to work with only a opto-mechanical interface to main unit **1603**. In another embodiment, sensor cassette **1605** may optionally include a small battery power supply in case of power failure.

In one embodiment, sensor cassette **1605** may be either attached or inserted into main unit **1603**. In the alternative, main unit **1603** may include an external sub-unit (not shown) that serves as the receiving interface for sensor cassette **1605**. Thus, sensor cassette **1605** can be placed in proximity to patient **1602** without limiting the size of main unit **1603**. In another embodiment, sensor cassette **1605** may optionally be attached to main unit **1603** by means of a data connector, an optional power connection means, and tubing.

The above examples are merely illustrative of the many applications of the system of present invention. Although only a few embodiments of the present invention have been described herein, it should be understood that the present invention might be embodied in many other specific forms without departing from the spirit or scope of the invention. Therefore, the present examples and embodiments are to be considered as illustrative and not restrictive, and the invention is not to be limited to the details given herein, but may be modified within the scope of the appended claims.

We claim:

1. A blood constituent measuring device comprising:

at least one fluid access interface configured to automatically interface with a patient blood access line at a sampling port to access a blood sample therefrom and to separate the blood sample from the patient blood access line, said at least one fluid access interface comprising a container configured to contain the blood sample separated from the patient blood access line;

a plurality of test substrates, wherein the at least one fluid access interface is configured to transfer each of a plurality of blood samples to each of the plurality of test substrates, wherein the at least one fluid access interface comprises a plurality of fluid access interfaces wherein each fluid access interface is configured to transfer a blood sample to a corresponding test substrate of the plurality of test substrates; and

at least one pump element configured to direct the separated blood sample to the corresponding test substrate.

2. The device of claim **1**, wherein the at least one fluid access interface is movable with respect to the sample port.

3. The device of claim **1**, wherein the device is configured to transfer the blood samples to the corresponding test substrates using a predetermined schedule.

4. The device of claim **1**, further comprising a housing containing said plurality of test substrates.

5. The device of claim **1**, further comprising an infusion source coupled to the patient blood access line.

6. The device of claim **1**, wherein the at least one pump element comprises a flexible portion configured to direct the separated blood sample to the test substrate.

7. The device of claim **6**, wherein the flexible portion is configured to contract.

8. The device of claim **7**, wherein the flexible portion is configured to expand.

9. The device of claim **1**, wherein the container comprises a tube.

10. The device of claim **1**, wherein the container comprises a valve.

11. The device of claim **1**, wherein the container comprises a cylinder.

12. The device of claim **1**, wherein the test substrate comprises a glucose test substrate.

13. The device of claim **1**, wherein the at least one pump element is further configured to pull the blood sample from the sampling port.

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